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Quebec-based Medicago begins Phase 3 trial for COVID-19 vaccine, first in Canada to reach large scale study

IVAN SEMENIUK > SCIENCE REPORTER

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A dose of a COVID-19 vaccine developed by Medicago is administered to a healthy woman participant in Quebec City on July 13, 2020 as part of the company's Phase 1 clinical trials.

MEDICAGO/THE CANADIAN PRESS

Medicago Inc. has launched a large-scale study to test its COVID-19 vaccine – a major step for the Quebec-based biopharmaceutical company that is aiming to play a role in curbing the coronavirus pandemic, even as other vaccines roll out in Canada and around the world.

On Tuesday, the company said it was moving forward with its Phase 3 clinical trial, the stage at which the efficacy of a vaccine can be reliably measured.

The study aims to enroll 30,000 participants from 10 countries, including Canada, the United States and Britain. That could pose a challenge when it come to recruiting in countries where authorized vaccines are now becoming available to older and high-risk individuals. To ensure that a wide range of participants takes part, the trial will include sites in Eastern Europe and Latin America where vaccines are relatively scarce and where the disease risk remains high for those who are in older age groups. Meanwhile, the relentless pace of the pandemic everywhere has made it all but certain that the trial can be conducted in a reasonable amount of time.

“COVID hasn’t gone away,” said Brian Ward, Medicago’s medical officer. “We are thinking that there will be plenty of cases for us to prove the efficacy of our vaccine in the next short while.”

If the trial proceeds smoothly, Dr. Ward said initial results could be ready later this spring. That would be the point at which the company could request that Health Canada review its vaccine for potential authorization, opening the door for widespread distribution.

“This is of course great news for Canadians,” said federal Science and Industry Minister François-Philippe Champagne during a news briefing.

Canada vaccine tracker: How many COVID-19 doses have been administered so far?

Last year, Ottawa signed a deal to buy 20-million doses of the Medicago vaccine with an option to purchase 56 million more. The vaccine involves a unique technology in which the proteins that signal the immune system to fight the coronavirus are manufactured in tobacco plants. The company has limited capacity to produce the vaccine in Canada, at the rate of approximately one-million doses per month, until a new facility is completed in 2023 or 2024. Much of its current production capacity is in North Carolina.

Of the six vaccines that the federal government has currently made agreements to purchase, Medicago’s is the only one being developed in Canada. It is also the last to reach a Phase 3 trial. With shots of some vaccines already being delivered to Canadians, Dr. Ward said the Medicago trial will need to run somewhat differently than the Phase 3 studies that were conducted to test the others.

For example, when the Pfizer-BioNTech, Moderna and AstraZeneca vaccines were in Phase 3 trials last fall, each trial randomly gave a placebo to one half of its participants and the real vaccine to the other half. Neither the investigators nor the participants knew who had the real vaccine. After the trial had run for a period of months, investigators could compare the two groups and see how much protection the vaccine had provided.

Medicago's trial will start out the same way, with each participant receiving two doses spaced 21 days apart. Half of the participants will receive a placebo. Then, after a certain interval of time, the two groups will flip and be inoculated a second time with two more doses. Those who received the placebo at first will then receive the real vaccine and vice versa. No one will know which group they belong to until the entire study is over. By then, every participant will have received the real vaccine, while a comparison of the groups will reveal the vaccine's efficacy.

In order to achieve their statistical target, investigators will need to wait until 160 study participants have tested positive for COVID-19 before the flip can occur.

Dr. Ward said that participants who become eligible for an authorized vaccine before the flip will have the option to find out if they are in the group that has already been vaccinated.

Whether the vaccine can be authorized soon enough to influence the course of the pandemic in Canada depends on several factors. For example, it may be used as a booster if it turns out that people require periodic re-immunization. It may also prove to be a vaccine of choice for children and pregnant women because it is given with an adjuvant made by the global pharma company GlaxoSmithKline that already has an established safety record in those groups.

Last summer, Medicago's vaccine was the first in Canada to be tested in people. Since then, nearly 1,000 individuals have been enrolled in Phase 1 and Phase 2 trials and the vaccine performed well in terms of safety and at generating an immune response, Dr. Ward said. Laboratory studies are also under way to test the vaccine against variants of the coronavirus. So far, those studies suggest that high antibody levels in the blood of individuals who received the vaccine continue to confer protection against severe disease.

At Dawson Clinical Research in Guelph, Ont., one of the Phase 2 study sites, Marianne Roth, manager of clinical operations, said she and her colleagues were pleased with the results they saw. They are now working to enroll up to 300 individuals as part of the Phase 3 trial.

“It’s monumental,” she said of Medicago’s milestone. “It’s been a lot of work but we’re really proud to be part of something Canadian, that’s for sure.”

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351 King Street East, Suite 1600, Toronto, ON Canada, M5A 0N1

Phillip Crawley, Publisher